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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/331,261	06/18/99	PEREGRINO FERREIRA	P	41823

HM22/1021

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EXAMINER	
ZEMAN, R	

ART UNIT	PAPER NUMBER
1643	5

DATE MAILED: 10/21/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/331,261	Ferreira et al
Examiner	**Group Art Unit**
Robert A Zeman	1643

☒ Responsive to communication(s) filed on *Jun 18, 1999* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-3* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-3* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities:

The sentence "....or beads followed by eletrotransferred or transferred passively in the these concentrations to nitrocellulose or nylon supports." (See page 6 lines 4-6) is confusing and illogical.

Appropriate corrections are required.

Claim Objections

Claim 1 is objected to because of the following informalities: Claim does not end with a period. Additionally, Claim 1 recites the word "unbounded" which is not idiomatic English. Suggest that "unbound" be used instead of "unbounded". Appropriate correction is required.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Brazil on 12/18/96. It is noted, however, that applicant has not filed a certified copy of the priority application as required by 35 U.S.C. 119(b). It is noted that the copy of the foreign priority document has not been forwarded by the International Bureau. Applicant is requested to provide a copy of said document.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention employs the use of a recombinant gp90 protein. The specification does not set forth procedures for obtaining or making gp90 recombinantly. The specification is completely lacking in the disclosure of appropriate sequences, vectors, expression systems or procedures for making recombinant gp90 usable in the invention. One of ordinary skill in the art would not be able to follow the procedures set forth in the specification to make and use the invention as claimed with a reasonable expectation for success and without undue experimentation based on the scanty guidance provided in applicant's specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

OK Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

OK Claim 1 is indefinite since step (a) does not describe an active process. Changing "the use of " to "providing" is suggested. Additionally, the final step of the process as described in (f) does not correlate with the preamble of the claim. "Detecting the presence of...." is not equivalent with "measuring amount of....."

OK Claims 2 and 3 are rejected as they recite improper Markush language, rendering the claim indefinite. Proper language for claim 2 would be "....label is selected from the group consisting of an enzyme, a fluorescent marker **and** biotin marker."

OK Claim 3 is confusing. There is no logical grouping or delineation between the listing of the various solid supports and the materials of which they are comprised.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al. (U.S. Patent 5,427,907) in view of Reis et al. (Reis et al, 1996 GENBANK ACC. NO. U53453) and Ball et al. (Journal of Virology, 1992 Vol. 66 pp. 732-742).

Claims 1-3 recite an immunoenzymatic assay for detecting antibodies to Equine Infectious Anemia Virus (EIAV).

Peterson et al. disclose an assay that uses recombinant gp45 as the bound antigen for the detection of antibodies to EIAV. Peterson et al. also disclose the procedures for binding the recombinant gp45 antigen to a solid support; for reacting the bound antigen with a test sample of serum; for removal of unbound test sample; for reacting bound test antibody with a labeled conjugate; and for the measurement of bound antibody to EIAV gp45. Peterson et al. used recombinant gp45 in their assay because the technique of culturing a virus increases the likelihood that the assay would yield false positive results since the virus may be contaminated with other forms of protein. Additionally the EIA virus is hard to culture making it difficult to use this approach for large scale production. Peterson et al disclose an assay for the detection of

the EIA virus which can be quickly and easily performed using a pure source of antigen thus reducing the problem of false positive results. Peterson et al. however does not disclose the use of recombinant gp90. Ball et al. (Journal of Virology, 1992 Vol. 66 pp. 732-742) disclose that gp90 is a highly immunogenic surface glycoprotein of EIAV and as such is an attractive target for immunoassays. Reis et al. (Reis et al, 1996 GENBANK ACC. NO. U53453) disclose the sequence for a recombinant gp90 antigen . Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the recombinant gp90 disclosed by Reis et al in the EIAV detection assay of Peterson et al. because recombinant EIAV protein offers a safer and more pure form of the protein.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al. (U.S. Patent 5,427,907) in view of Ball et al. (Journal of Virology, 1992 Vol. 66 pp. 732-742).

Claims 1-3 recite an immunoenzymatic assay for detecting antibodies to Equine Infectious Anemia Virus (EIAV).

Peterson et al. disclose an assay that uses recombinant gp45 as the bound antigen for the detection of antibodies to EIAV. Peterson et al. also disclose the procedures for binding the recombinant gp45 antigen to a solid support; for reacting the bound antigen with a test sample of serum; for removal of unbound test sample; for reacting bound test antibody with a labeled conjugate; and for the measurement of bound antibody to EIAV gp45. Peterson discloses an assay for detecting EIAV using recombinant gp45. Peterson et al. used recombinant gp45 in their assay because the technique of culturing a virus increases the likelihood that the assay

would yield false positive results since the virus may be contaminated with other forms of protein. Additionally the EIA virus is hard to culture making it difficult to use this approach for large scale production. Peterson et al disclose an assay for the detection of the EIA virus which can be quickly and easily performed using a pure source of antigen thus reducing the problem of false positive results. Peterson et al. however does not disclose the use of recombinant gp90. Ball et al. (Journal of Virology, 1992 Vol. 66 pp. 732-742) disclose that gp90 is a highly immunogenic surface glycoprotein of EIAV and as such is an attractive target for immunoassays. Additionally, Ball et al. (Journal of Virology, 1992 Vol. 66 pp. 732-742) disclose the full sequence for gp90. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the gp90 disclosed by Ball et al in the EIAV detection assay of Peterson et al. because synthesized EIAV protein offers a safer and more pure form of the protein.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al. (U.S. Patent 5,427,907) in view of Payne et al. (Virology, 1989 Vol. 172 pp. 609-615) and Ball et al. (Journal of Virology, 1992 Vol. 66 pp. 732-742).

Claims 1-3 recite an immunoenzymatic assay for detecting antibodies to Equine Infectious Anemia Virus (EIAV)

Peterson et al. disclose an assay that uses recombinant gp45 as the bound antigen for the detection of antibodies to EIAV. Peterson et al. also disclose the procedures for binding the recombinant gp45 antigen to a solid support; for reacting the bound antigen with a test sample of serum; for removal of unbound test sample; for reacting bound test antibody with a labeled conjugate; and for the measurement of bound antibody to EIAV gp45. Peterson discloses an assay for detecting EIAV using recombinant gp45. Peterson et al. used recombinant gp45 in their assay because the technique of culturing a virus increases the likelihood that the assay would yield false positive results since the virus may be contaminated with other forms of protein. Additionally the EIA virus is hard to culture making it difficult to use this approach for large scale production. Peterson et al disclose an assay for the detection of the EIA virus which can be quickly and easily performed using a pure source of antigen thus reducing the problem of false positive results. Peterson et al. however does not disclose the use of recombinant gp90. Ball et al. (Journal of Virology, 1992 Vol. 66 pp. 732-742) disclose that gp90 is a highly immunogenic surface glycoprotein of EIAV and as such is an attractive target for immunoassays. Payne et al. (Virology, 1989 Vol. 172 pp. 609-615) disclose the full sequence for recombinant gp90. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the recombinant gp90 disclosed by Payne et al in the EIAV detection assay disclosed by Peterson et al. One would have been motivated to use a recombinant form of the gp90 as it offers a safer and more pure form of the protein..

Conclusion

No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032.

DONNA WORTMAN
PRIMARY EXAMINER

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October 20, 1999